SUMMARY: The Food and Drug Administration (FDA) is publishing a notice announcing that it has received a petition requesting exemption from the premarket notification requirements for the total triiodothyronine test system class II device (special controls). FDA is publishing this notice in order to obtain comments on this petition in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments by August 10, 2000.

ADDRESSES: Submit written comments on this notice to the Docket Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of the FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142). In the **Federal Register** of November 3, 1998 (63 FR 59222), FDA published a final rule codifying these exemptions.

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the Internet on the CDRH home page at http://www.fda.gov/cdrh or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Petition

FDA received the following petition requesting an exemption from premarket notification for class II devices:

Abbott Laboratories, *Total triiodothyronine test system*, 21 CFR 862.1710.

IV. Comments

Interested persons may submit to the Docket Management Branch (address above) written comments regarding this petition by August 10, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 28, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–17389 Filed 7–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. 00N–0504]

Egg Safety; Current Thinking Papers on Egg Safety National Standards; Notice of Availability; Public Meeting

[Docket No. 98–045N4]

AGENCIES: Food and Drug Administration, HHS; Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) and the Food

Safety and Inspection Service (FSIS) are announcing the availability of the agencies' current thinking papers on national standards for egg safety. The documents discuss approaches to the production of shell eggs, processing and packaging of shell eggs and egg products, and retail sale of shell eggs, including immediate consumption, such as at a restaurant, intended to reduce the risk of consumer exposure to *Salmonella enteritidis* (SE). The current thinking papers represent the agencies' current views on approaches to ensure egg safety from farm to table. FDA and FSIS are also announcing a joint public meeting to be held to discuss the current thinking papers.

DATES: The current thinking papers will be presented and distributed at a public meeting on July 31, 2000. The public meeting will be held on Monday, July 31, 2000, from 8 a.m. to 5 p.m. Submit written comments no later than August 14, 2000.

ADDRESSES: The meeting will be held at the Holiday Inn—Washington, DC on the Hill, 415 New Jersey Ave. NW., Washington, DC 20001, 202–638–1616.

After the meeting, the current thinking papers on egg safety national standards will be available on the Internet at www.foodsafety.gov, or from Tammy O'Conner, USDA/FSIS/OPPDE/RDAD, rm. 112, Cotton Annex Bldg., 300 12th St. SW., Washington, DC 20250–3700, FAX 202–205–0381, or FDA's Center for Food Safety and Applied Nutrition Outreach and Information Center, FAX 877–366–3322.

Transcripts and summaries of the meeting will be available at the Dockets Management Branch (HFA–305), FDA, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *To register for the meeting:*

Sally Fernandez, FSIS, 202–501–7251 or FAX 202–501–7615. When registering please provide name, title, firm name, address, telephone, and fax number. When registering, please indicate if you would like to make a presentation during the meeting. Time allotted for each presentation will be approximately 5 minutes for each participant, but will depend on the number of people participating. If you require a sign language interpreter or other special accommodations, please notify Ms. Fernandez 7 days before the meeting.

For general information regarding the meeting or the Egg Safety Action Plan: Nancy Bufano, FDA, 202–401–2022, FAX 202–205–4422, or e-mail: nancy.bufano@cfsan.fda.gov; Alice Thaler, FSIS, 202–690–2683, FAX 202–720–8213; or Martha Workman, FSIS, 202–720–3219, FAX 202–690–0824.

SUPPLEMENTARY INFORMATION:

I. Background

The President's Council on Food Safety was established in August 1998 to improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs. The Council on Food Safety was charged with developing a comprehensive long-range strategic plan that can be used to set priorities, improve coordination and efficiency, identify gaps in the current system, recommend ways to fill those gaps, enhance and strengthen prevention and intervention strategies, and identify or develop measures to show progress.

The Council has identified egg safety as one component of food safety that warrants immediate Federal, interagency action. In July 1999, FDA and FSIS committed to developing an action plan to address the presence of SE in shell eggs and egg products using a farm-to-table approach.

As part of this action plan, FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on draft goals, as well as to further develop objectives and action items. The Egg Safety Action Plan, announced by the President on December 11, 1999, was developed, in part, from the input received at the meeting. The Egg Safety Action Plan is available on the Internet at www.foodsafety.gov or from the general information contact persons above.

The information shared at the public meeting and during the comment period following the public meeting will be considered prior to any further actions by the agencies. The agencies may hold additional public meetings, as appropriate, to discuss other issues, including strategies to ensure effective and efficient interactions between State and Federal governments.

II. Decision to Make Current Thinking Papers Available for Comment

On March 30, 2000, and April 6, 2000, the agencies held public meetings in Columbus, OH, and Sacramento, CA, respectively, to solicit and discuss information related to the implementation of the Egg Safety Action Plan and to gather information for reducing or eliminating the risk of SE in eggs. Transcripts from both meetings are available on the Internet at www.foodsafety.gov or from FDA's Dockets Management Branch (address above), at a cost of 10 cents per page. The summaries of the public meetings are also available for public examination at FDA's Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Based on verbal comments received at the meetings, written comments received subsequent to the meetings, and the desire to promote public participation in the implementation of the Egg Safety Action Plan, FDA and FSIS decided to publish this notice of availability of the agencies' current thinking papers in the **Federal Register**.

The current thinking papers represent the agencies' current views on approaches to ensure egg safety from farm to table. FDA and FSIS are soliciting public comment on these documents to obtain views as to whether the agencies are implementing the Egg Safety Action Plan in a way that will best achieve its public health goals.

III. Opportunity for Public Meeting

The agenda for the public meeting will address the following segments of the farm-to-table egg safety continuum: (1) On-Farm Production, (2) Packer/Processor, and (3) Retail. The agenda will also provide for discussion of economics issues, as well as small business and consumer perspectives.

Attendees are encouraged to present their comments, concerns, and recommendations on any of these topics at the public meeting. Attendees wishing to make a presentation must indicate such when registering.

Individuals and organizations that do not preregister to make a presentation may have the opportunity to speak if time permits. A transcript of the proceedings of the public meeting, as well as all information and data submitted voluntarily to FDA and FSIS during the public meeting to discuss the current thinking papers, will become part of the administrative record and will be available to the public under 21 CFR 20.111 from FDA's Dockets Management Branch (address above).

While oral presentations from specific individuals and organizations will be limited during the public meeting, the written comments submitted as part of the administrative record may contain a discussion of any issues of concern. All relevant data and documentation should be submitted with the written comments.

IV. Additional Public Notification

Public awareness of and involvement in all segments of rulemaking and policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce the

notice and provide copies of this **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at http://www.fsis.usda.gov. The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience. For more information and to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office at 202–720–5704.

V. Public Dockets and Submission of Comments

The agencies have established public dockets to which comments may be submitted. Comments should be directed either to FSIS, Docket No. 98–045N4, or to FDA, Docket No. 00N–0504, or to both dockets for consideration by both agencies. All comments must include the appropriate docket number found in brackets in the heading of this document. Submit written comments in triplicate to: (1) USDA/FSIS Docket Clerk, 300 12th St. SW., rm. 102, Cotton Annex, Washington, DC 20250-3700, or (2) FDA's Dockets Management Branch (address above). You may also send comments to Dockets Management Branch at the following e-mail address: FDADockets@oc.fda.gov or via the FDA Internet at http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm.

VI. Meeting Summary

A summary of the proceedings of the public meeting will be posted on the Internet at www.foodsafety.gov. This website is a joint FDA, USDA, and Environmental Protection Agency food safety home page. It is linked to each agency for persons seeking additional food safety information. A summary of the proceedings of the public meeting may also be requested in writing from FDA's Dockets Management Branch (address above) approximately 30 business days after the meeting, at a cost of 10 cents per page. The summary of the public meeting will be available for public examination at FDA's Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 5, 2000.

Thomas J. Billy,

Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation, Food and Drug Administration.

[FR Doc. 00–17494 Filed 7–10–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–730 & 182]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New Collection;

Title of Information Collection: Employee Building Pass Application and File;

Form No.: HCFA–730 & 182 (OMB# 0938-NEW);

Use: The purpose of this system and the forms are to control United States Government Building Passes issued to all HCFA employees and non-HCFA employees who require continuous access to HCFA buildings in Baltimore and other HCFA and HHS buildings;

Frequency: Other; as needed;

Affected Public: Federal Government, and Business or other for-profit;

Number of Respondents: 150;

Total Annual Responses: 150;

Total Annual Hours: 37.50.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 28, 2000.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 00–17477 Filed 7–10–00; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF THE INTERIOR

Fish And Wildlife Service

Endangered and Threatened Species: Incidental Take Permits—Houston Toad

Notice of Availability of an Environmental Assessment/Habitat Conservation Plan and Receipt of an Application for a Permit for the Incidental Take of the Houston toad (*Bufo houstonensis*) During Construction of One Single Family Residence on 0.5 acres of the 5.087-Acre Lot 41, Section 1 in the KC Estates Subdivision, Bastrop County, Texas (Bush).

SUMMARY: Anthony V. Bush (Applicant) has applied to the U.S. Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(a) of the Endangered Species Act (Act). The Applicant has been assigned permit number TE–029602–0. The requested permit, which is for a period of 5 years, would authorize the incidental take of the endangered Houston toad (*Bufo houstonensis*). The proposed take would occur as a result